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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,057	04/03/2002	Seiko Hirano	221519USOPCT	6859

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,057	HIRANO ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-44,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,46 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/1/04; 3/2/04; 7/22/02; 4/3/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group XXXVII, (Claims 45-46, and 49 drawn to a DNA which codes for SEQ ID NO: 80) in the reply filed on May 5, 2004 is acknowledged. The traversal is on the ground(s) that as set forth in MPEP, Annex B, part 2, Example 17, which sets forth that a "protein and the DNA sequence exhibit corresponding special technical features." Applicants further assert that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. Finally Applicants assert that the Office has not shown that a burden exists in searching the entire application.

This is not found persuasive because first, as set forth in MPEP, Annex B, part 2, Example 17, a protein and the DNA sequence exhibit corresponding special technical features only when the prior art does not disclose of them in the first place. As set forth below, Applicants will find a rejection under 35 USC 102 of the claimed DNA sequence which destroys any special technical feature. Furthermore, Applicants are directed to their own claims and sequence listing. The claims clearly recite a "protein having the amino acid sequence of SEQ ID NO: 80." (See claim 45) However, Applicants sequence listing recites a nucleotide sequence for SEQ ID NO: 80. Accordingly, any argument of special technical features between DNA and protein are irrelevant, since both SEQ ID NO: 79 and 80 are nucleotide sequences. Applicants further assert that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. However, the Examiner has not subjected the

claims to any national law. Given that the claimed sequence is disclosed in the prior art, unity of invention is found to be lacking and restriction is appropriate. Finally, Applicants assert that the Office has not shown that a burden exists in searching the entire application. However, given that each protein comprises a separate primary, secondary, and tertiary structure, each of the sequences would require a separate search and consideration of the art, a reference which anticipates one protein would not necessarily anticipate or render obvious any other sequence. Accordingly, a search of the entire application would represent a burden.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 45-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 45-46 are directed to nucleic acids which have the same characteristics and utility as nucleic acids found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered.

Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated nucleic acid..."

2. Claims 45-46 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 45-46 and 49 are directed to DNA which codes for a protein having the amino acid sequence of SEQ ID NO: 80, including substitutions, deletions, insertions, addition or inversion of one or several amino acids; or DNA hybridizable to SEQ ID NO: 79, or primers prepared based upon the nucleotide sequence under a stringent condition.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 79 alone is insufficient to describe the genus. Furthermore, since SEQ ID NO: 79 is not a full length open reading frame, written description is satisfied only for the recited fragment

(i.e., consisting of SEQ ID NO: 79), since additional nucleotides upstream or downstream would have a tremendous impact upon the activity of the encoded protein. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

3. Claims 45-46 and 49 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "the amino acid sequence of SEQ ID NO: 80." One of skill in the art would be unable to determine the metes and bounds of the claimed invention since Applicants sequence listing recites a short nucleotide sequence for SEQ ID NO: 80.

4. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "stringent condition." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. Stringency is determined by the physical and chemical conditions under which the hybridization takes place as well as subsequent washing steps. However, without some guidance as to the physical and chemical conditions which are deemed "stringent" as opposed to conditions considered non-stringent, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 45-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Eikmanns et al.

The claims are directed to a DNA which codes for a protein having the amino acid sequence of SEQ ID NO: 80, including substitution, deletion, insertion, addition or inversion of one or several amino acid residues. Applicants claim further defines the sequence as comprising

SEQ ID NO: 79, or hybridizable to SEQ ID NO: 79.

As noted above, SEQ ID NO: 80 is a short nucleic acid sequence, accordingly the limitation of a protein "having the amino acid sequence of SEQ ID NO: 80" cannot be determined. Accordingly, the remaining limitations have been considered.

Eikmanns et al (Journal of Bacteriology Vol. 177, No. 3, pp 774-782, Feb. 1995) disclose of an isolated DNA sequence comprising SEQ ID NO: 79, as well as recombinantly expressing the encoded protein. (See abstract and Figure 3).

In view that Eikmanns et al disclose of a DNA sequence which is 100% structurally identical to the instantly claimed DNA, the disclosure of Eikmanns et al is deemed to anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
July 6, 2004